REMARKS

Claims 1-16, 18-50 and 52-60 are currently pending in this application. Claims 1-16, 18-27, 52-56 and 59 stand withdrawn. Claim 28 and several other claims are amended herein and claim 45 is canceled. New claim 61 is directed to a subject matter similar to that of claim 28, and therefore falls within the scope of the subject matter of the provisionally elected claims of Group VI. Support for new claim 61 is found in the specification as a whole, e.g., on page 12, lines 1-3. Upon entry of this response with amendments, claims 1-16, 18-44, 46-50 and 52-61 will be pending. Support for amended claim 28 can be found throughout the application as originally filed, *inter alia*, on page 15, lines 27-30.

Restriction Requirement

Applicants note that the Office Action states that Applicants' arguments regarding traversal of the restricted claims were considered, but were not persuasive. As a result, the Office Action has held claims 1-16, 18-27, 52-56 and 59 as withdrawn from consideration.

Applicants respectfully submit, however, that claims 1-16, 18-21, 52-56 and 59, as amended in the Preliminary Amendment filed on December 1, 2003, are directed to methods of treating symptoms or diseases caused by estrogen deficiency, where the patient has or is at risk of having breast cancer, comprising administering a composition comprising an admixture of an extract of *Cimicifuga racemosa* or derivatives thereof and a pharmaceutically acceptable carrier, and that the subject matter of these claims is consistent with the subject matter of claims 28-49 and 57-58, provisionally elected by Applicants in their Response to Restriction Requirement filed on September 29, 2003. Thus, claims 1-16, 18-21, 52-56 and 59 should be examined together with the elected claims.

This is underscored by the fact that claim 60, which ultimately depends from claim 1 and incorporates the subject matter of claims 1 and 59, was examined on the merits in the February 11, 2003 Office Action. Applicants respectfully submit, therefore, that examination of claim 60 on the merits is consistent with Applicants' assertion that claims 1-16, 18-21, 52-56 and 59 involve the same or corresponding technical feature as claims 28-49 and 57-58. The same applies to claims 24 and 25 for all the reasons set forth in the aforementioned Response and Preliminary Amendment, and Applicants respectfully request examination of claims 1-16, 18-21, 24,25, 52-56 and 59 on the merits, as such examination is consistent with the subject matter of the provisionally elected claims of Group VI and the examination of claim 60 on the merits.

Rejections

Rejections under 35 U.S.C. § 112, 1st Paragraph

Claims 28-50, 57-58 and 60 were rejected under 35 U.S.C. § 112, 1st paragraph, as allegedly failing to comply with the enablement requirement. More specifically, the Office Action states that the disclosure has no description of the claimed invention. *See* Office Action, Page 2, lines 21-24. According to the Office Action, the specification is not enabled for thousands of known steroidal estrogens, and that one skilled in the art could not practice the methods of the invention without undue experimentation. The Office Action also takes the position that the specification has no description of the claimed invention, *i.e.*, a method of curing or relieving "symptoms," or "diseases" caused by estrogenic deficiency or which can be relieved or cured by administration of "steroidal estrogen" *Id.* The claims were also rejected for the alleged lack of enablement of the same claim language.

Applicants respectfully disagree and traverse this rejection.

It is well established under 35 U.S.C. §112 ¶ 1, that "[t]he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." (*United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1986)). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976), MPEP § 2164.01. The factors to be considered in determining whether a disclosure would require undue experimentation include: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability of the art, and (8) the breadth of the claims." *In re Wands*, 858 F.2d 731, 773 (Fed. Cir. 1988).

Applicants respectfully submit that the rejected claims (prior to their amendment herein) were enabled by the specification since persons of ordinary skill in the art would not have needed to engage in undue experimentation to make or use the full scope of the claims, if they read the specification. Such persons would also have understood that Applicants had possession of the claimed invention when the application was filed.

Nonetheless, in the interest of expediting prosecution, Applicants have amended claim 28 to more particularly recite the subject matter of the invention, by inclusion of the element

"...comprising substances, or at least one derivative of such substances, included in a *Cimicifuga racemosa* extract said extract being obtainable by vortexing *Cimicifuga racemosa* material in an aqueous solution..." Applicants respectfully submit that the subject matter of amended claim 28, and necessarily all claims depending therefrom, is fully supported and enabled by the specification as originally filed. For example, the specification, on page 15, lines 27-29, provides enabling description for the generation of *Cimicifuga racemosa* extract. In addition, the specification on page 10, line 33 extending to page 11, line 8, and Example 9, provides a recitation of estrogen-deficiency related conditions or symptoms to which the extract may be administered for treatment. The specification also provides, on page 37, lines 2-3, a dosing regimen of *Cimicifuga racemosa* extract.

Accordingly, Applicants submit that one of skill in the art is enabled to obtain *Cimicifuga racemosa* extract as claimed herein, and Applicants have identified and disclosed estrogen-deficiency related disorders or conditions to which said extract may be administered for treatment. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 28-50, 57-58 and 60 under 35 U.S.C. § 112, 1st paragraph, as allegedly failing to comply with the enablement and written description requirements.

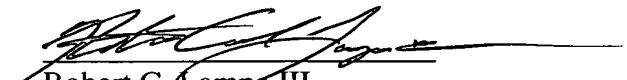
CONCLUSION

Applicants submit that claims 1-16, 18-21, 24,25, 28-49 52-56, and 59-61 are in condition for allowance for all the reasons discussed above. Early notification of a favorable consideration and allowance of all claims are respectfully requested. In the event any issues remain, Applicants would appreciate the courtesy of a telephone call to their counsel to resolve such issues and place all claims in condition for allowance.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Dated: June 14, 2004

By: 

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